PV REGULATIONS IN RCT

Investigational VS observational

Investigate something new VS observe drug in its approved conditions

Volume 10 guidance VS volume 9A (GVP)

SO

Volume 10 scope = collection, assessment, reporting of adverse reactions which occur in clinical trial SO also distinguish between IMP investigational medicinal product & non-IMP (which compared with it)

Reporting of SUSARS

Suspected unexpected serious adverse reactions.

Adverse reactions – causality:

All untoward and unintended responses to investigational drug related to any dose administered.

Also cover medication errors and uses outside what is in protocol, also misuse and abuse of the product.

Clock zero = time receive SUSARs

If new information received on previously received case, **clock zero** start again = reported as follow up report

MINIMUM INFORMATION TO REPORTING

1- Suspected IMP

2- Identifiable subject (study subject code number)

3- AE assessed as serious & unexpected with accepted causal relationship.

4- Identifiable reporting source.

MINIMUM INFORMATION TO REPORTING

5- Unique case identifier (sponsor case identification number).

6- protocol number of study.

7- CIOMS-I form used as standard format in the absence of electronic reporting.

MINIMUM INFORMATION TO REPORTING at least all of the following

Sponsor study number – one identifiable coded subject - one identifiable reporter – one SUSAR – one subject IMP (active name & code) – causality assessment.

MINIMUM INFORMATION TO REPORTING

to report electronically

Case safety report unique identifier.

Receive date of initial information from primary source.

Receive date of most recent information.

Worldwide unique case identification number.

Sender identifier.

Causality – Expectedness

Seriousness & causality assessed by reporting investigator.

Expectedness usually done by sponsor = SmPC or IP

Reporting of relevant information:

1- Sponsor must report all relevant information necessary to verify therapeutic and public health benefits continue to justify risks.

2- But also medical and scientific judgments need to be applied in identifying relevant & non relevant information.

3- New administrative information may impact on the case management (must be considered relevant) – detect potential duplicate.

4- Non- relevant information are minor changes of dates or corrections of typographical error in last version of case report.

Reporting time line:

1- SUSARs are not fatal & not life-threatening = reported within 15 days.

2- SUSARs initially considered non-fatal, non-serious then turned to be fatal or serious must be reported as soon as possible, if not applicable must be reported within 15 days

Duplicate reports:

1- Each report & follow up must have sufficient information to identify duplicates such as: unique case identifier – unique patient identifier.

2- Date of onset can be useful to identify duplicates.

3- Identified duplicate reports must be reported to regulatory authority

4- SOPs – training plan must be in place to avoid duplicates.

Problem identified --- root/cause analysis--- CAPA plan to be put in place.

Follow up reports:

1- Follow up must be done for validation step.

2- Follow up for additional information to complete case assessment.

3- Special follow up needed for = pregnancies, death, treatment failure.

Follow up reports:

1- Follow up must be done for validation step.

2- Follow up for additional information to complete case assessment.

3- Special follow up needed for = pregnancies, death, treatment failure.

Thanks a lot for your kind cooperation & nice interactions in our PV sessions.

HOPE A LOT OF SUCCESS TO ALL OF YOU

Dr Walaa Arafa